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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KINSEY, NICOLE	
ART UNIT	**PAPER NUMBER**
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,640	HOLLAND ET AL.	
	Examiner	Art Unit	
	Nicole E. Kinsey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) *13-22,25-35,41-46,53 and 54* is/are withdrawn from consideration.

5)☒ Claim(s) *1,3,4,7-12,23,24,36,39,40,47,49-52 and 55* is/are allowed.

6)☒ Claim(s) *2,5,6,37,38,48 and 56* is/are rejected.

7)☒ Claim(s) *2,6,37,48 and 56* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/21/2004 & 12/1/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' election with traverse of Group I (claims 1-6, 23-24, 36-40, 47-52, 55 and 56) in the reply filed on December 21, 2006 is acknowledged. The traversal is on the grounds that i) a phage produced by the method of claims 7 and 11 falls within the scope of claims 1 and thus the claims of Groups II and III should be included with the claims of Group I; ii) Groups I and IV-VII are not independent or distinct and iii) the Examiner has not provided any discussion or support indicating why the methods of Groups II-VII are independent or distinct.

For traversal i), applicants' arguments are found persuasive, and the claims of Groups II and III will be rejoined with the claims of Group I.

For traversal ii), applicants' arguments are not found persuasive. The inventions of Group I and Groups IV-VII are related as product and process of use. According to the MPEP, the inventions can be shown to be distinct if either or both of the following can be shown: (1) **the process for using the product as claimed can be practiced with another materially different product** or (2) the product as claimed can be used in a materially different process of using that product: See MPEP § 806.05(h). In the instant case, the methods of Groups IV-VII are to i) remove Methylobacteria from a plant by reducing or eliminating the bacteria; ii) treat a Methylobacteria or HBB infection in a patient by reducing or eliminating Methylobacteria or HBB; iii) disinfecting a surface by reducing or eliminating Methylobacteria or HBB; and iv) treat an HBB infection, respectively. All of the methods listed above can be carried out with another materially different product. For example, antibiotics against Methylobacteria (and HBB) can be

used to i) remove Methylobacteria from a plant by reducing or eliminating the bacteria; ii) treat a Methylobacteria or HBB infection in a patient by reducing or eliminating Methylobacteria or HBB; iii) disinfecting a surface by reducing or eliminating Methylobacteria or HBB; and iv) treat an HBB infection. Thus, the requirements of MPEP § 806.05(h) have been met.

For traversal iii), applicants' arguments are not found persuasive. Applicants argue that the Examiner simply recited what each group is drawn to without any discussion or support describing why the methods of each group are independent or distinct. In the Office Action dated September 21, 2006, the Examiner recited what each group is drawn to in addition to reciting the requirements for each method.

Group II, which is drawn to a method of purifying a bacteriophage, which is lytic for Methylobacteria, requires plating and infecting Methylobacteria with a bacteriophage. Group III, which is drawn to a method of purifying a bacteriophage, which is lytic for HBB, requires plating and infecting HBB with a bacteriophage. Group IV, which is drawn to a method of removing Methylobacteria from a plant, a method of producing male sterility in a plant, and a method of obtaining hybrid seeds of a plant, requires contacting a plant or seed with a bacteriophage. Group V, which is drawn to a method of treating a Methylobacteria or HBB infection in a patient and a method of treating an HBB associated autoimmune disease in a patient, requires administering a bacteriophage to a patient. Group VI, which is drawn to a method of disinfecting an environmental surface contaminated with Methylobacteria or HBB, requires contacting a surface with a bacteriophage. Group VII, which is drawn to a method of making a

medicament containing a bacteriophage, requires mixing a bacteriophage with other ingredients to formulate the medicament. Thus, because each Group requires different starting materials and different steps to carry out the method and because each Group has a different objective and final outcome, each Group is independent or distinct. Furthermore, each Group, being independent or distinct, would require a separate search, which would present a search burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Status of Claims

Claims 1-12, 23-24, 36-40, 47-52, 55 and 56 are under examination, and claims 13-22, 25-35, 41-46 and 53-54 are withdrawn from further consideration.

Claim Objections

Claims 2, 6, 37, 48, and 56 recite either "the bacteriophage is present in ATCC #PTA-5075" or "the bacteriophage is selected from ATCC #PTA-5075." Applicants should amend these claims to recite "wherein the bacteriophage is deposited as ATCC #PTA-5075" for clarity.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for progeny of the bacteriophage deposited in ATCC #PTA-5075, does not reasonably provide enablement for derivative recombinant forms or recombinant mutated forms of the bacteriophage deposited in ATCC #PTA-5075. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)).

Nature of the invention. The claim is drawn to derivative recombinant forms and recombinant mutated forms of the bacteriophage deposited in ATCC #PTA-5075.

State of the prior art. At the time the invention was made, there was no teaching in the art for making derivative recombinant forms or recombinant mutated forms of the bacteriophage deposited in ATCC #PTA-5075.

Breadth of the claims. The claims are very broad, encompassing any phage that is lytic for Methylobacterium or HBB including recombinant phages and phages that have any mutation(s).

Working examples. There are no working examples of any derivative recombinant phages or recombinant mutated phages that are lytic for Methylobacterium or HBB.

Guidance in the specification. The specification provides no guidance regarding practice of the claimed invention. The specification does not indicate how to make

recombinant or mutant phages that still retain the ability to lyse Methylobacterium or HBB. There is no guidance in the specification as to where certain mutations (or deletions, insertions, or substitutions) can be made within the phage genome such that the phage can still lyse Methylobacterium or HBB.

Given the breadth of the claim, the state of the prior art, the lack of guidance in the specification, and the lack of working examples, it would require undue experimentation for one skilled in the art to make or use the claimed invention.

Claims 2, 6, 37, 48 and 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that PTA-5075 is required to practice the claimed invention. As such, PTA-5075 must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of PTA-5075.

The phages disclosed in the specification do not appear to be produced from a repeatable process, and it is not apparent if the phages are both known and readily available to the public. It is noted that page 4 of the specification indicates that the

phages have been deposited; however, there is no indication in the specification as to public availability.

If the deposit was made under the terms of the Budapest Treaty, then a statement, affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, or someone empowered to make such a statement, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement.

If the deposit was not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CRF 1.801-1.809 and MPEP 2402-2411.05, applicants may provide assurance of compliance by statement, affidavit or declaration or by someone empowered to make the same or by a statement by an attorney of record over his or her signature and registration number showing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 does not recite proper Markush language (i.e., "and" instead of "or").

Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 requires the addition of an antibiotic to the pharmaceutical composition of claim 36. The metes and bounds of the antibiotic are not clearly set forth because the claim does not indicate what the antibiotic is for. It is not clear if applicants mean any antibiotic or an antibiotic that is effective against Methylobacterium and/or HBB.

Allowable Subject Matter

Claims 1, 3-4, 7-12, 23-24, 36, 39-40, 47, 49-52 and 55 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole E. Kinsey, Ph.D. whose telephone number is

(571) 272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nicole E Kinsey, Ph.D.
Examiner
Art Unit 1648

Stacy B Chen 1/30/07

STACY B. CHEN
PRIMARY EXAMINER